Complete Summary

GUIDELINE TITLE

Special treatment situations: alternative headache treatments. Standards of care for headache diagnosis and treatment.

BIBLIOGRAPHIC SOURCE(S)

Mauskop A, Graff-Radford S. Special treatment situations: alternative headache treatments. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 115-22. [21 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Primary headaches including:

- Migraine (with or without aura)
- Tension-type headache (TTH)
- Cluster headache
- Chronic daily headache (CDH)
- Chronic tension-type headache (CTTH)
- New daily persistent headache
- Hemicrania continua

GUIDELINE CATEGORY

Management Prevention Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Neurology

INTENDED USERS

Health Care Providers Physicians

GUIDELINE OBJECTIVE(S)

- To improve the medical treatment of headache
- To provide recommendations on the newer, or alternative, approaches to managing headache

TARGET POPULATION

Patients diagnosed with primary headache

INTERVENTIONS AND PRACTICES CONSIDERED

Alternative Headache Treatments

- 1. Patient education
 - Provision of printed materials
 - Discussion of trigger factors
 - Setting realistic treatment expectations
- 2. Herbal remedies and supplements
 - Feverfew
 - Butterbur root extract (Petadolex®)
 - Riboflavin
 - Coenzyme Q₁₀
 - Magnesium
- 3. Botulinum toxin type A (Botox®)
- 4. Transcutaneous electrical nerve stimulation (TENS) (considered, but not recommended)
- 5. Vagus nerve stimulation (VNS) (considered, but not recommended)
- 6. Cold or pressure application
 - Application of fluoromethane vapocoolant spray
- 7. Acupuncture
- 8. Use of intraoral dental appliances
- 9. Manipulative treatment (i.e., chiropractic and osteopathic care) (considered, but not recommended)
- 10. Physical therapy
- 11. Cognitive behavioral therapy

- 12. Psychiatric therapy (considered, but not recommended, except in patients with coexisting psychiatric disorder)
- 13. Biofeedback
- 14. Relaxation training
- 15. Hypnosis
- 16. Neural blockade
- 17. Exercise
- 18. Homeopathy (considered, but not recommended)

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines presented in this monograph represent the consensus of an advisory panel of practitioners chosen by the National Headache Foundation (NHF) for their expertise. In addition to incorporating the US Headache Consortium's recommendations, their conclusions reflect clinical experience and the most recent medical literature.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Alternative Headache Treatments

Once patients have received an accurate diagnosis and been reassured that their attacks are not caused by a secondary or more serious pathology, clinicians and patients should work together to identify the most appropriate treatment plans. Although pharmacologic management presents many effective options, the therapy of most patients can be optimized with the addition of various nonpharmacologic approaches. This chapter looks at some of the newer, or alternative, approaches to managing headache. These approaches are summarized in the table below.

Alternative Headache Treatments	
TREATMENT	EFFECTI VE/SAFE
Feverfew	Yes/Yes
Butterbur root extract (Petadolex®)	Yes/Yes
Riboflavin	Yes/Yes

Alternative Headache Treatments	
TREATMENT	EFFECTIVE/SAFE
Magnesium	Yes/Yes
Botox®	Possible/Yes
Transcutaneous electrical nerve stimulation (TENS)	No/Yes
Cold application	Possible/Yes
Intraoral appliances	Possible/Guarded
Acupuncture	Yes/Yes
Manipulative treatment	No/Questionable
Physical therapy	Possible/Not known
Cognitive behavioral treatment	Yes/Yes
Biofeedback	Yes/Yes
Relaxation therapy	Yes/Yes
Nerve blocks	Possible/Some risks
Homeopathy	No/Yes

Patient Education

Patient education (see National Headache Foundation guideline on "Patient Education") is an essential component of any treatment plan. Migraine patients should be given a basic explanation of the physiologic etiology of headache. Printed materials are an effective way to educate patients about the role of genetic predisposition, as well as the relationship between headache and the central nervous system, the peripheral nervous system, and vascular and humeral mechanisms. Patients' knowing that their attacks are a real and treatable condition may enhance compliance with therapy and ultimately improve the chance for a successful treatment outcome.

Trigger factors (see table below) should be discussed; these may be different for each patient. Clinicians should work with patients to set realistic treatment expectations, with an emphasis on management, not cure, and should encourage patients to remain active partners in their treatment throughout its course.

Some Potential Triggers of Migraine Headache

- Emotional stress
- Changes in behavior: missing meals, changes in sleep duration
- Environmental factors: light, noise, odors, allergens, barometric changes

Some Potential Triggers of Migraine Headache

- Foods and beverages: chocolate, cheese, cured meats, caffeine beverages, alcohol
- Chemicals: aspartame, monosodium glutamate, benzene, insecticides, nitrates
- Drugs

Herbal Remedies and Supplements

Herbal remedies remain very popular, in part because they are perceived to be natural and therefore safer than prescription drugs. This perception is often not accurate, as the Food and Drug Administration (FDA) does not regulate herbal and nutritional remedies. One herb that appears to be safe and possibly effective in the prevention of migraine headaches is feverfew. This herb has been subjected to double-blind trials and has an extensive safety record. A second herbal remedy, butterbur root extract (the only purified form of this extract is sold as Petadolex) has 2 published trials of safety and efficacy. Herbal remedies have the potential to interact with prescription drugs and should always be used under a physician's supervision. Specifically, feverfew can cause increased bleeding time and enhance the effect of aspirin and warfarin. Because of lack of regulation, patients should use only products manufactured by large and reputable companies.

Riboflavin (vitamin B_2) has been studied at doses of 400 mg per day (divided), and although it can take several months to provide optimal efficacy, it may benefit some patients with migraine. There are no known significant adverse effects. Coenzyme Q_{10} , another supplement, has been subjected to one open-label trial that suggested efficacy; the results were later confirmed in a double-blind trial using a 300 mg dose. Magnesium has been studied extensively, both for acute treatment intravenously (IV) and for preventive treatment. The IV acute studies suggest it may be effective for treating acute attacks of migraine. In oral doses of 400 to 600 mg per day, the results of 3 of the 4 double-blind studies were strongly positive. The negative study had a very high incidence of diarrhea, which suggests that the magnesium salt used in this study was poorly absorbed. Magnesium oxide and chelated magnesium tend to be better tolerated.

Botulinum Toxin Type A

Botulinum toxin type A (Botox® [Btt A]) was approved by the FDA in 1989 for the treatment of blepharospasm and strabismus. Widespread use of Btt A for the treatment of forehead wrinkles (approved by the FDA in 2002) led to the discovery of its efficacy in relieving headaches. Many anecdotal reports and several controlled trials confirm the efficacy of Btt A in preventing migraine headaches. The effect of a single Btt A treatment lasts an average of 3 months. The procedure takes 5 to 10 minutes and causes minimal discomfort. Approximately 10 to 20 sites are injected at each session. The dosage and the location of the sites to be injected remain subject to continuing study. In general, the number and the location of the injection sites depend on pain distribution and the presence of trigger points. Side effects from Btt A injections are very rare and mild.

Transcutaneous Electrical Nerve Stimulation (TENS)

The use of TENS has been reserved primarily for the treatment of body or extremity pains because of fear of potential epileptogenic effects of electric current running through the head. With proper placement of electrodes and the use of low-intensity currents, it appears to be safe to apply this technique to the head. However, there is little objective evidence about the efficacy of TENS. Considering the inconvenience and the limited efficacy, this treatment is not recommended.

Vagus Nerve Stimulation (VNS)

VNS is an approved procedure for the treatment of drug-refractory epilepsy. Several case reports and indirect evidence from epilepsy trials suggest that VNS may also be effective in the treatment of refractory migraines. That anticonvulsants are effective in the prevention of migraines suggests that VNS may also work in migraines. However, in the absence of a controlled trial, it is premature to recommend this treatment for migraine headaches.

Cold or Pressure Application

Cold or pressure application to the head has been shown to be an effective headache strategy. Application of vapocoolant spray (fluoromethane) has been demonstrated to decrease myofascial pain in tension-type headache. The use of cold gel packs is beneficial as a self-help technique.

Acupuncture

Although there is no consensus in the clinical literature to support the efficacy of acupuncture, studies have shown that some patients experience significant pain relief. A meta-analysis of 14 controlled trials of acupuncture indicates a strong trend in favor of acupuncture.

Intraoral Dental Appliances

Intraoral dental appliances have also been used to treat headache, but more definitive studies are needed. The patient should be made aware of the risks associated with intraoral splint therapy other than conventional full arch coverage stabilization devices.

Chiropractic, Osteopathic Medicine, and Physical Therapy

The value and cost-effectiveness of chiropractic, osteopathic medicine, and physical therapy in migraine have not been proven in clinical trials. Conflicting results and poor clinical trial design limit the ability to judge the effectiveness of manipulative treatments. Physical therapy, although limited in its study, has proven more effective than manipulative treatment in selected cases.

Cognitive Behavioral Therapy (CBT)

CBT is designed to help patients identify and change maladaptive behaviors that may be aggravating the headaches. CBT is usually combined with other behavioral therapies but has been shown to be effective on its own. The goals are to identify the maladaptive thoughts, develop an action plan to deal with the headache, and encourage long-term implementation of the techniques. CBT is discussed in detail in a separate guideline titled "Behavioral Interventions for Management of Primary Head Pain".

Psychiatric Therapy

Psychiatric therapy is not indicated, except in patients with coexisting psychiatric disorder.

Biofeedback

Biofeedback refers to the use of monitoring instruments to detect, amplify, and display internal physiologic processes, so the patient may learn to alter the process at will. Patients should be selected based on their motivation, as well as equipment availability. A meta-analysis has indicated that the benefit of biofeedback is similar to that of prophylactic therapy. Biofeedback may also serve as an excellent adjunct to pharmacologic therapy. Biofeedback is discussed in detail in a separate guideline titled "Behavioral Interventions for Management of Primary Head Pain."

Relaxation Training

Relaxation training is a biobehavioral approach that involves progressive muscle relaxation, breathing exercises, or imagery. A meta-analysis has suggested that relaxation is as effective as biofeedback. The treatment may be enhanced by combining relaxation and biofeedback and adding pharmacologic intervention where appropriate. Patients should be selected if they are motivated and likely to use the techniques. Relaxation training is discussed in detail in a separate guideline titled "Behavioral Interventions for Management of Primary Head Pain."

Hypnosis

Hypnosis may be an excellent tool in a small subgroups of patients who are willing to undergo the procedure and suitable for it.

Neural Blockade

Neural blockade--occipital, supraorbital, sphenopalatine ganglion, stellate ganglion, cervical facet, epidural, etc.--may serve a diagnostic or therapeutic role in headache patients. The specific role of neural blockade in migraine and tension-type headache may be more limited to occipital or supraorbital block in the acute stage when the pain is localized. The effect of this procedure may be only to change what is being perceived by the brain, however, and does not imply that the pain is generated from the structure injected. Trigger point injections to the muscles of mastication or the cervical muscles may also aid the therapeutic outcome.

Exercise

The benefits of exercise are generally accepted. Sleep may be improved with regular exercise, and that in turn helps headache. It is also suggested that routine exercise may enhance central pain inhibition. Although there are no specific studies showing a direct relationship between exercise and headache, developing an appropriate exercise regimen with the patient is encouraged.

Homeopathy

Homeopathy has not proven effective in controlled clinical trials. Even if safe, it may not provide any specific benefit beyond a placebo effect.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

In addition to incorporating the US Headache Consortium's recommendations, the conclusions reflect clinical experience and the most recent medical literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of alternative headache treatments

POTENTIAL HARMS

Herbal remedies have the potential to interact with prescription drugs and should always be used under a physician's supervision. Specifically, feverfew can cause increased bleeding time and enhance the effect of aspirin and warfarin.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Drug therapy is constantly evolving as new research, clinical trials, case reports, and opinions are published. Many of the drugs recommended in these guidelines are not approved by the US Food and Drug Administration (FDA) for treatment of headache, nor are they necessarily the same as those therapies recommended by the manufacturer for labeled indications. Their use in headache, however, may be supported by the scientific literature and by the authors' clinical experiences. While efforts have been made to ensure accuracy, the authors and publisher do

not assume responsibility for the consistent updating of available information for these guidelines, nor for any errors or omissions, nor for any consequences thereof. The onus is on the practitioner to evaluate recommendations in light of the clinical condition of the patient and recent medical literature. The authors advise the practitioner to consult other sources, especially the manufacturers' warnings and precautions, before prescribing any drug with which they are unfamiliar. Practitioners are also advised that while these guidelines will address the needs of many patients, there will be circumstances calling for exceptions to these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Foreign Language Translations
Patient Resources
Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mauskop A, Graff-Radford S. Special treatment situations: alternative headache treatments. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 115-22. [21 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

National Headache Foundation - Private Nonprofit Organization

SOURCE(S) OF FUNDING

National Headache Foundation

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Alexander Mauskop, MD, FAAN, and Steven Graff-Radford, DDS

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The complete headache chart. Chicago (IL): National Headache Foundation (NHF); 2 p. Electronic copies available in Portable Document Format (PDF) from the National Headache Foundation Web site
- National Headache Foundation fact sheet. Chicago (IL): National Headache Foundation (NHF); 2004 Oct. 2 p. Electronic copies available in Portable Document Format (PDF) from the <u>National Headache Foundation Web site</u>.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

PATIENT RESOURCES

The National Headache Foundation (NHF) has created a variety of educational resources for patients, including informative brochures, a patient diary for migraines, Power Point presentations, and patient guides; many of these resources are available in both Spanish and English. Some of these items are available as print copies for purchase through the NHF online store. Electronic versions of other resources are available through the consumer education section of the NHF Web site.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on April 13, 2005. The information was verified by the guideline developer on April 26, 2005.

COPYRIGHT STATEMENT

These guidelines are for reference purposes only and are not to be mass produced. This information is copyrighted by the National Headache Foundation, 2005.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse $^{\text{TM}}$ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2006 National Guideline Clearinghouse

Date Modified: 10/9/2006